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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,668	11/17/2006	Nathalie Mougin	128322	5008

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
03/04/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/582,668	MOUGIN ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/12/06 and 09/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of the species: coil polymeric block structure: propylene oxide; rod polymeric block structure: poly(L-glutamic acid); copolymer configuration: rod-block-coil di-block in the reply filed on 12/7/10 is acknowledged. The traversal is on the grounds that election of species is a convention specific to US patent practice. Applicant's arguments have been carefully considered but not deemed persuasive for the reasons of record (p. 2-3 of Office Action dated 11/9/2009) and consideration of MPEP 1893.03(d) which discusses the Patent Cooperation treaty and addresses species under 371.

Further, Examiner does confirm that upon search, examination and allowance of the elected species, search and examination will continue.

The election of species requirement is still deemed proper and is therefore made FINAL.

Status of the claims

2. Claims 1-35, 38 are pending in the application. Claims 1, 16, 34-35 have been amended. Applicant indicates that claims 4, 6, 10, 14 are not drawn to the elected species. However, upon searching, other species were found encompassed by the instant claims which are herein examined for the sake of compact prosecution and which are deemed to read upon those claims. Therefore, all the pending claims, i.e., claims 1-35 and 38 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rendered vague and indefinite deemed unclear because when p=0 then the formula II becomes A-[COCH-NH]n-B, and therefore the carbon has three bonds only attached to it.

Claim 6 recites the limitation, e.g., "poly-(gamma-benzyl-L-glutamate)", e.g., see lines 9-11. There is insufficient antecedent basis for this limitation in the claim, since the claims have been amended so that the peptide motifs have free hydrogen atoms with some or all of the free hydrogen atoms of the peptide motifs participating in non-covalent hydrogen bonds within the rod structure and poly-(gamma-benzyl-L-glutamate) does not meet that requirement.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-15, 17-19, 24-35, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Thunemann et al. (Macromolecules, 2000).

Thunemann et al. disclose a composition comprising at least one rod-coil type block copolymer comprising at least one "coil" polymeric block structure of variable conformation (i.e., PEG, polyethylene oxide) bonded to at least one "rod" block structure of restricted conformation (i.e., PLL, poly-L-lysine), wherein:

the at least one rod-coil type block copolymer is provided in a physiologically acceptable medium (water, retinoic acid); and

the rod block structure is of polymeric nature and is constituted in full or in part of peptide motifs having free hydrogen atoms with some or all of the free hydrogen atoms of the peptide motifs participating in non-covalent hydrogen bonds within the rod structure.

Thunemann et al. teach that complexes of polyethylene oxide -*b*- poly(L-lysine) block copolymers with retinoic acid with short poly(L-lysine) segments of 18-30 monomers form core shell micelles. This effective stabilization of the alpha-helix structure seems to be due to the formation of a protective surrounding coat of retinoate and a shell of poly(ethylene oxide). Vitamin A and its analogues, in particular retinoic acid, are involved in the proliferation and differentiation of epithelial tissues and have continued to be used in the treatment of dermatological disorders such as acne, psoriasis and hyperkeratosis (e.g., p. 5908) and therefore is cosmetically compatible (i.e., reads upon cosmetic). The composition of Thunemann et al. is considered useful in the development of drug delivery formulations (e.g., abstract). The limitation drawn to the convention of claims 2 and 9 would be inherent to the composition of Thunemann et al. since it anticipates the structural limitations of the claims 1, 3, and 5. Thunemann et

al. teach aqueous solutions 0.5-5 % w/w (e.g., p. 5909). For complex formation 0.1 g of retinoic acid was dissolved in 40 mL of water at pH 9. One equivalent of PEO-PLL18 and PEO-PLL30 were each dissolved in 15 mL of water (pH 9.0). The samples were prepared by letting droplets of diluted aqueous solutions (0.01% w/w) dry on fresh cleaved muscovite mica surfaces at room temperature. Please note that retinoic acid reads upon a fatty phase as it contains a large non-polar component and that micelles are inherent to emulsions. Further, retinoic acid reads upon a particulate filler and/or pigment. The number average molecular mass of the rod blocks was determined as follows:MW of lysine is 146, PLL18 is about 2322 g/mol, calculated 146x18-18x17 to account for the polymerization water. The number average molecular mass for PEO is 5000 g/mol, therefore the weight ratio of the rod block is 31% relative to the total weight of the copolymer. The copolymer overall number average molecular weight would be 7322 g/mol.

With regards to the limitations “wherein the composition is in the form of a makeup and/or a care product for the skin and/or the lips", “wherein the composition is in the form of a product that has been cast as a stick or a cake" and "the composition is in the form of a care product and/or a makeup for the nails”. MPEP 2111.04 states “Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) “ adapted to ” or “adapted for ” clauses;

(B) " wherein " clauses; and

(C) " whereby " clauses.

The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case." In the instant cases it is not clear as to whether the composition has any structural changes per se that would distinguish from the product taught by Thunemann et al. since it anticipates all the structural limitations set forth in the claims.

With regards to the limitations "cosmetic", "surface active agent", "rheological agent" and "block copolymer of the rod-coil type" which appear in the preamble of the claims, it appears that they do not impart any structural limitation beyond that set forth in the body of the claim. Therefore, since the composition of Thunemann et al. anticipates all the structural limitations set forth in the body of the claim, such preambles are not deemed to introduce a any weight. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (MPEP 2111.02).

Therefore the reference is deemed to anticipate the instant claims above.

7. Claims 1-6, 9-11 14-15, 17, 29-35, 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kwon et al. (Pharmaceutical Research, 1999).

Kwon et al. teach that soluble block copolymers may self-assemble into novel supramolecular structures, which possess functional properties for drug delivery. These unique molecular architectures are being researched for the delivery of anticancer drugs, proteins and plasmid DNA. A major consideration of these drug delivery systems

is their nanoscopic dimensions, which may yield advantages in terms of drug targeting, safety and developments. Moreover, there has been substantial progress in their chemistry, and we can now envision biocompatible, biodegradable synthetic analogues of biological transports systems, lipoproteins or viruses. Some of the block copolymers are: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L) Amino Acid, PEO-*b*-PLL (wherein PLL is poly-L-lysine). The compounds meet the structural limitations of claim 1, including having solubility in water, e.g. p. 597-8 which reads upon a physiologically acceptable medium.

With regards to the limitations “wherein the composition is in the form of a makeup and/or a care product for the skin and/or the lips", “wherein the composition is in the form of a product that has been cast as a stick or a cake" and "the composition is in the form of a care product and/or a makeup for the nails”. MPEP 2111.04 states “Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. However, examples of claim language, although not exhaustive, that may raise a question as to the limiting effect of the language in a claim are:

(A) “ adapted to ” or “adapted for ” clauses;

(B) “ wherein ” clauses; and

(C) “ whereby ” clauses.

-to whether the composition has any structural changes per se that would distinguish from the product taught by Kwon et al. since it anticipates all the structural limitations set forth in the claims.

With regards to the limitations "cosmetic", "surface active agent", "rheological agent" and "block copolymer of the rod-coil type" which appear in the preamble of the claims, it appears that they do not impart any structural limitation beyond that set forth in the body of the claim. Therefore, since the composition of Kwon et al. anticipates all the structural limitations set forth in the body of the claim, such preambles are not deemed to introduce a any weight. The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim (MPEP 2111.02).

Therefore the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 9-11, 14-15, 17, 29-35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon et al. (Pharmaceutical Research, 1999) in view of Wiley et al. (US 5,470,510).

Kwon et al. is relied upon as above. Kwon et al.'s disclosure includes some block copolymers such as: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L-Amino Acid), PEO-*b*-PLL (wherein PLL is poly-L-lysine) for drug delivery and being soluble in the physiological medium water (e.g., p. 597-8).

Kwon et al. do not expressly teach the poly(L)amino acid being Poly (L-glutamic acid).

Willey et al. teach poly(glutamic acid) may be used to make homopolymers of glutamic acid and block copolymers with biodegradable monomers or polymers such as PEO (e.g., abstract, Col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make complexes PEO-*b*-PLAA, wherein PLAA is poly(glutamic acid). One of ordinary skill in the art at the time the invention was made would have been motivated to do in order to make delivery agents taught by Kwon to be PEO-*b*- p. 5907PLAA wherein PLAA could be any amino acid. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success since Willey et al. taught that poly(glutamic acid) could be used to make homopolymers of glutamic acid and block copolymers with biodegradable monomers or polymers such as PEO (e.g., abstract, col. 2).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 1-6, 9-11 14-15, 17-35, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwon et al. (Pharmaceutical Research, 1999) in view of Cooper et al. (WO 95/22991, cited in the IDS dated 6/12/06).

Kwon et al. is relied upon as above. Kwon et al.'s disclosure includes some block copolymers such as: A poly(ethylene oxide)-block-poly(aspartic acid) (PEO-*b*-PAA (e.g., p. 597), PEO-*b*-PLAA (wherein PLAA is a Poly(L) Amino Acid, PEO-*b*-PLL (wherein PLL is poly-L-lysine) for drug delivery and being soluble in the physiological medium water (e.g., pages. 597-8).

Kwon et al. do not expressly teach the PEO being substituted for polypropylene oxide.

Cooper et al. teach linear block copolymer comprising units of an alkylene oxide (including propylene oxide, see page 6), linked to units of peptide via a linking group useful as imaging agent, drug, prodrug or as delivery system. (e.g., pages. 1-10). Also Cooper et al. teach the compositions may have adsorbents such as kaolin and bentonite, fillers or extenders such as starches, sucrose, glucose, mannitol, and silicic acid. Liquid dosage forms may include emulsifiers, other solvents such as oils, particularly cottonseed oil, groundnut oil, olive oil, castor oil, fatty acid esters, etc. (p. 36). Compositions may include cocoa butter or wax (e.g., page 37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the compound of Kwon by using polypropylene oxide as taught by Cooper et al. in order to obtain other useful delivery agents. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to make other delivery agents since both Kwon et al. and Cooper et al. teach the same generic parameters of making delivery agents with alkylene oxide and a peptide.

One of ordinary skill in the art at the art the invention was made would have had a reasonable expectation of success since Cooper et al. teaches a wide variety of peptides could be used with the propylene oxide (e.g., pages 7-8).

With regards to the limitations drawn to relative weight of the solid fat in the fatty phase, or the relative weight of the particulate phase, such limitations are not expressly taught. However, "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." (See MPEP 2144.05).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marcela M Cordero Garcia/
Examiner, Art Unit 1654

MMCG 02/2010